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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,932	07/29/2002	Frank Luyten	50304/027001	1230

21559	7590	01/14/2008
CLARK & ELBING LLP		
101 FEDERAL STREET		
BOSTON, MA 02110		

EXAMINER
WOOD, AMANDA P

ART UNIT	PAPER NUMBER
1657	

NOTIFICATION DATE	DELIVERY MODE
01/14/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary

Application No.

10/089,932

Applicant(s)

LUYTEN ET AL.

Examiner

Amanda P. Wood

Art Unit

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-36, 39-41, 43-47 and 49-61 is/are pending in the application.
- 4a) Of the above claim(s) 29-30, 39-41, 46-47, 49-50, 52-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31-36, 43-45, 51 and 55-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 22 October 2007 has been entered.

Claims 31-36, 43-45, 51, and 55-61 have been examined on the merits.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 31-36, 43-45, 51, and 55-61 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over 3-15, 27, 30, and 33 of copending Application No. 10/422,475. Although the conflicting claims are not identical, they are not patentably distinct from each other because a method for identifying cells having chondrocyte phenotypic stability comprising assaying the cells for expression of positive and/or negative markers of phenotypic stability, detecting the expression of the markers by sets of DNA probes, and therapeutic compositions comprising cells identified by the claimed assay method.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant made no arguments regarding the Obviousness-type Double patenting rejection of record, but Applicant did acknowledge the rejection and agreed to address it upon the indication of otherwise allowable subject matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 31-36, 43-45, 51, and 55-61 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains

subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In particular, claims 31 recites a method for determining expression by chondrocytes of positive marker, wherein the positive markers are BMP-2 and/or FGFR-3, and identifying cells expressing said positive markers as cells having chondrocyte phenotypic stability.

It would appear from the teachings of Yayan et al (WO 96/41620) that the marker FGFR-3 (a positive marker, as taught in the instant specification) is indicative of mesenchymal skeletal progenitor cells, which can differentiate into bone and/or cartilage, and therefore, that FGFR-3 would be insufficient as a positive marker by itself to indicate cells having chondrocyte phenotypic stability. Therefore, the teachings of Yayan et al indicate that to differentiate between mesenchymal skeletal progenitor cells, which would have only FGFR-3 expressed, and chondrocytes, one would need to identify markers in addition to FGFR-3 on chondrocytes for identifying cells having chondrocyte phenotypic stability. Applicant's disclosure teaches that FGFR-3 is always determined with at least one other marker, whether it is col type 2, BMP-2, ALK-1, or some combination thereof. Based upon the teachings of Yayan et al, and the Applicant's disclosure, the instantly claimed method as drafted would need to require at least the determination of both FGFR-3 and the negative marker ALK-1, to identify chondrocytes as having chondrocyte phenotypic stability. Therefore, Applicant is not enabled for a method wherein only FGFR-3 is determined, based upon both the teachings of Yayan et al, and the teachings found within the Applicant's own disclosure.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, first paragraph for the reasons set forth above.

Response to Arguments

Applicant's arguments filed 22 October 2007 have been fully considered but they are not persuasive. In particular, Applicant argues that the teachings of Yayon et al are misleading and irrelevant to the interpretation of the Applicant's specification. Furthermore, Applicant does admit that it is clear that FGFR-3 is not solely expressed on chondrocytes but is expressed by different cell types. In addition, Applicant states that the inventors have found that in chondrocytes, FGFR-3 is not constitutively expressed, but its expression is linked to the ability of the chondrocyte cells to produce stable hyaline cartilage. The Examiner respectfully disagrees with Applicant's arguments that Yayon et al is irrelevant to Applicant's disclosure. In particular, the fact that FGFR-3 is not solely expressed on chondrocytes indicates the very reason why Applicant should not be enabled for a method wherein only FGFR-3 is used as the positive marker to be determined by its expression. Furthermore, Applicant's own disclosure teaches that FGFR-3 is determined along with other markers to identify stable chondrocytes, instead of just using FGFR-3. In fact, Applicant teaches in Example 8 that the optimal way to select cells for autologous cell transplant is to identify both FGFR-3 and ALK-1 to obtain populations of stable cells and unstable chondrocytes within the total pool using FACS analysis.

Conclusion

No claims allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda P. Wood whose telephone number is (571) 272-8141. The examiner can normally be reached on M-F 8:30AM -5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

APW
Examiner
Art Unit 1657

APW


CHRISTOPHER R. TATE
PRIMARY EXAMINER